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ABSTRACT

Current regulatory trends, policies, and procedures greatly affect social studies research using human subjects and evaluation of that research. The legal source of protection of human subjects is the National Research Act of 1974. The law stipulates that rights of research subjects must be protected and that the responsibility is on the researcher to inform the subject of procedures and possible consequences of the research. Problems occur because local review boards monitor the research activities of their organizations. They have the potentiality to extend and abuse their role through their power to define what constitutes research and to determine what research they can control. In reference to some policies and procedures instituted by human subjects committees of educational institutions, it appears that the rights of researchers themselves are violated. In regulating research, possibilities of violation of the first amendment, the American system of justice, and academic freedom exist. Social studies research is affected by reduction in the amount of experimental research and the number of subjects involved, and by the fact that subjects must have prior knowledge of the purpose, nature, and direction of the research. Also, a great deal of time and money must be spent in obtaining consent. The conclusion is that any external control of the research community should not go by unchallenged. (KC)

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PROTECTION OF HUMAN SUBJECTS: IMPLICATIONS FOR
SOCIAL STUDIES RESEARCH

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Protection of Human Subjects: Implications for Social Studies Research

This paper is chiefly concerned with the possible effects of federal regulations and the implementing policies and procedures of local institutions with regard to research with human subjects. The primary assumption of the paper is that since basic research in social studies education is essentially concerned with human subjects, regulation of such research by those external to the profession should be taken seriously. The thesis of the paper is that current regulatory trends, policies and procedures are having a revolutionary effect upon the research that the community of social studies scholars is doing and that which they are capable of doing, as well as on the summative and formative evaluation related to that research.

Brief History of the Regulation of Research with Human Subjects

The beginning point of much of the regulations and policies governing research with human subjects has been the Declaration of Helsinki, a document prepared by the World Medical Association. The principles and standards set forth in this document were not intended to replace, substitute for, or guide criminal and civil, responsibilities. They were simply to serve as a guide to medical doctors engaged in clinical research. The Declaration emphasized that the health of the patient should be the first consideration. It further stipulated that in non-therapeutic research the nature, purpose, and risk should be explained to the "patient" and that the patient must give consent in writing while mentally and legally in a free-choice "capable state." Psychological as well as psychiatric medical practices were not only considered in this document, but paramount. Freedom to withdraw permission by the patient was also stipulated as a condition for consent.

Though it was not the intent of this Declaration to dictate legislation, it stimulated thinking in legal circles. The major legal source of protection

of research with human subjects in the United States is derived from the National Research Act (Public Law 93-348) enacted by Congress in July of 1974. This law in effect stipulated that protection of rights of research subjects must be protected and placed responsibility upon the researcher to inform the subject of his/her rights. Rules and regulations relating to protection of human subjects were developed by the Department of Health, Education and Welfare and published in the Federal Register on March 13, 1975.* Following a rather familiar strategy, the department used the power to withhold federal grants and contracts as the "teeth" of the regulations, guaranteeing compliance. The policy formulated in the guidelines included as its major feature the allocating of responsibility of protecting human subjects involved in any research primarily with the educational institutions. Any institution which wanted to be considered for funds from the Federal Government was, in fact, sure to comply and develop an approved policy.

An institution review board was stipulated in the plan. This board was to certify as approved any research activity which was submitted to D.H.E.W. which involved human subjects. The review was to establish if subjects would be placed "at risk" and, should this be so, if risks were outweighed by benefits. Both the rights and welfare of subjects had to be protected and a legal, effective, and informed consent procedure guaranteed. Consent of subjects meant that they not only knowingly agreed to the procedure but knew the possible consequences that might occur. The review board was also to look for assurance of review of the conduct of the activity involved. The researcher had to do what he or she

* The Federal Register. Vol. 40, No. 50, Thursday, March 13, 1975.

said they were going to . The regulations specifically stipulated that grants or contracts would be made only to individuals affiliated with institutions which could and did assume responsibility for protection of subjects. Each institutional review board was required to submit to the Department of Health, Education and Welfare, a set of general assurances describing the procedures for review and evidence of their implementation.

Institutional Implementation

Most organizations involved in education have quickly developed procedures for protecting subjects of research. Unfortunately, to all appearances the great hanging sword of governmental support and governmental grants and the threat of suit have been more powerful motivators in this accomplishment than any real concern for justice to subjects. However, this may be unfair. In many instances these procedures and the human zealotry in implementing them has far exceeded the charge and the responsibility. There have been repeated overreactions and instances where local review boards have exceeded their authority in development of local policies from suitable open ended guidelines. Excessive zeal or fear has caused institutional moves without consideration of consequences or ramifications. One of these may be that review committees have been endued with power to accept or deny all research proposals within institutions whose pronounced purpose is to do research. Such authority has tended to create a substantial "power-base" for the individuals involved in its administration. Bureaucratic types of individuals appear to know how to embellish this type of power and to extend and accumulate it. No process of appeal of the committee's decision is required by the D.H.E.W. regulations. Substantially, the individual researcher or research group has no recourse but to submit to any "requests" that the committee makes.

Review boards may even extend their authority in two ways. First, as an approval granting group they can examine not only those questions related to protection of human subjects in a research proposal, but look at the total design of that research. This is, perhaps, a natural tendency since boards are composed mostly of individuals interested in research with human subjects themselves and involved in research design questions. A second extension of power, is that the committees define what constitutes research and over what research they have power. A major policy question relates to identification and definition of "risk" and "jeopardy" to the student. When is a student at risk? A second question is - What is research? Most review boards look not only at funded research, but at all research activities involving any employee of the institution either as principle researcher or as director. Such research in an institution of education includes all work done by students of staff members. Taken to its ultimate, these parameters may extend to all teaching-learning activities. Since no process of appeal has been regulated committee power becomes absolute. It creates a stifling deterrent to research and perhaps an invasion of the rights of a number of individuals.

I would contend that in some respects this regulatory instrumentation by institutions has failed to recognize that the researchers are themselves human beings possessing of rights. The protection of the rights on one group of individuals by the restriction of the rights of another relegates the second group to second class status. The following imputations might be arguable in reference to some restriction policies and procedures instituted by human subjects committees of educational institutions.

- (1) There exists a possibility of violation of the first amendment to the U.S. Constitution. This amendment guarantees to all citizens (including researchers) the rights of freedom of speech and of the press. When regulatory power is extended to reports in publications done at private expense or at no expense there is at least a suspicion that this right is in jeopardy.
- (2) There is often contradiction of that fundamental assumption of the American system of justice that a "criminal" is innocent until proven guilty. When the researcher is required to provide guarantees of protection of rights before the research is conducted, there is little question that guilt is assumed until innocence is proven.
- (3) There is a challenge to academic freedom implied by many of the powers delegated to or assumed by review boards.

The Nature of Change in Research

I stated earlier that regulations relating to human subjects would have a revolutionizing influence upon the nature of social studies research itself. I would like to advance three propositions regarding the nature of this change. First, the federal regulations and the implementing policies of local institutions are and will continue to reduce the amount of experimental research and the number of subjects involved in such research as well as other research efforts where the subjects will be considered at risk. Secondly, institutional bureaucracy created to implement the regulations has and will complicate and slow all research efforts where human subjects are involved. Thirdly, I would suggest that the regulations will effect research methodology and especially it has introduced an independent variable which will have varying and impossible to measure effect on individual studies. That variable is the forehand knowledge of the subjects of research concerning the purpose, nature and direction of the

research effort in which they are involved. I would like to discuss each of these propositions briefly noting some of the positive as well as negative ramifications of each.

Reduction in Experimental Research

The reduction of research of an experimental nature is almost an automatic conclusion. The federal regulations specifically add expense and difficulty to research effort. Informed consent adds to personnel time as much as paper cost. The supervisory procedures required are also costly.

In addition to the expense, parental consciousness is raised. Resentment caused by children being involved in research may be high. When dealing with minors such parental as well as student consent is legally required.

To many public school officials a policy of obtaining informed consent is a factor which offsets any benefit to students that the research might have. It eclipses any sense of professional obligation that they feel. I have talked to several public school administrators who were very negative about the requirements. One school official described the procedures as "parent harassment" and claimed that he would absolutely refuse any research project that required such parent consent. Others have said that they felt the requirements of permission that were required within the school system were sufficient and they would limit any current procedure within their framework. It does seem somewhat redundant to deal with the requirement of two educational organizations, but under the federal regulations this seems impossible to avoid unless one local authority abdicated its power to another.

Looking at Dissertation Abstracts I found support for the thesis that research with human subjects would decline due to the regulations. Simply examining the change in dissertations was revealing. I noted considerable change between 1970 and 1978. I would speculate that the percentage of

experimental studies has been considerably reduced and that far smaller samples are being used in more recent studies. It would be foolish to attribute any such change to the regulations alone, but their influence cannot be ignored.

On the positive side, the reduction of experimental research is not altogether undesirable. Lack of clarity in purpose, sometimes called mindlessness, has been a concern about both teaching and research in education. Shaver (1977, 1979), Larkin (1978), Suppes (1978) and Kerlinger (1973) are among those who have expressed concern that true impact of research upon education has been lacking. Larkin (1978) attributed the failure to a lack of true dedication to significance among researchers. Shaver (1979) stressed preoccupation with the "statistical premise," which he saw as difficult to change, dominating force in research in education. It may well be that the regulations of research with human subjects will bring greater care and concern for purposefulness and for clarification of purposes for that research which is conducted. At the same time a tighter control on the adherence of researchers to planned and pre-determined procedures is automatic. The information given to subjects as condition to their participation mandates that adherence.

An added effect may well be a reduction of the status of the "statistical bias," an acceptance of a broader range of research techniques, and a greater concern that research be of benefit to all subjects involved.

Effects of Local Bureaucratic Controls

I would like to deal with this question in a very cursory manner. The introduction of any single approval step in an institution of any size may cause projects to be delayed by as much as a month to a year. This is simply because the work involved in such steps is done by committees which meet monthly or less often. The need for the approval of the committee may mean that research

projects may need to be planned a year in advance from conception to implementation.

Methodological Effects

The major influencing factors in the regulation of research with human subjects which have to do with research methodology relate to the informed consent given by the subject of research and with sampling procedures.

Federal guidelines mandate proof from the researcher that subjects have willingly agreed to participate in any research study. Their agreement must be on the basis of informed consent. Informed consent means not only that subjects have not been coerced in any way into participation, but that any and all foreseeable consequences of their participation has been clearly described to them. In the case of minor subjects of research, the consent of the parent or legal guardian is required as well as, or instead of, the subject's own consent. This means that the participant may be coached at home or tutored. In any event, attitudes will be influenced in a variety of ways. The researcher must therefore spend a great deal of personel time in the obtaining of such consent and must build the questions surrounding it into design and analysis.

A major influence of the human subjects regulations is felt in the area of sampling or selecting research subjects for research efforts. Researchers in social sciences will need to act with considerably more caution and effort.

Informed consent is in itself a variable which eliminates the possibility of random selection from a total population. If the subjects of research not only know the purpose of treatment but agree to it they are at once different from those in the population who do not understand or agree. It should be noted that it is impossible under H.E.W. guidelines to determine what,

if any, effect prior knowledge of the purpose of a study has on the performance of subject in that study. Hawthornetype effects are unavoidable and, possible additional influences may result.

Positive influence upon methodology of research may be seen in clearer description of treatment and therapeutic consideration of all treatment groups including controls. The researcher may be required to account for the teaching-learning activity with those who refuse to participate. Thus the researcher must be a bit more serious in his/her intent to do the research for the benefit of the subjects - not just to complete a particular problem or solve a curiosity.

Conclusion

I am not disturbed that a fear of research and need to control research mood prevails in legislatures. The public is always suspicious of research and should be. Neither am I disturbed by the varying ramifications of human research regulation. As I have indicated in this paper there are positive aspects of this influence as well as negative. What does concern me is the profession's unquestioning acceptance of the legislation, the HEW guildlines and the local implementation. We have added to the growing pile of confused, whim controlled bureaucracy and external regulation that pervades our professional existence. We have quietly acquiesced to insistence on "non-decision making." This term was described (Bachrach and Bartz, 1962) as the "mobilization of bias" within an institution to prevent discussion of unsafe and undesirable questions, and avoid identification of issues and alternatives.

This paper has presented a very subjective overview of some of the issues involving possible effects of human subjects research. It would be easy to exaggerate this influence either by intent or accident. To do so would be unrealistic. The complexity of variables influencing research ought to be recognized as well as the rather questionable efficacy of past research.

Shaver (1979) for example, has questioned whether most studies have had any positive discernable impact upon education practices. Other researchers and educators have voiced equal skepticism about the research that has been done in the past.

Nonetheless, I do not feel that any external control or accusation of the research community should go by unchallenged and unquestioned. These particular controls seem to have passed with little more than grumbling, muttering complaint into bureaucratic reality. I maintain that it will influence future research greatly and that we need to take a very specific and careful look at just what the influence is going to do for the purposes of research themselves.

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